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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BELYAVSKYI, MICHAIL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/006,557

Applicant(s)

KING ET AL.

Examiner

Michail A Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

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## DETAILED ACTION

*Claims 1-39 are pending.*

### ***Restriction Requirement***

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-3, 20, 21, 22, 33, 34 and 35 drawn to a method of enhancing pericyte cell proliferation comprising administering to a subject in need a BPI protein product, wherein the subject is suffering from a complication of diabetes, classified in Class 424, subclass 185.1.
  - II. Claims 1, 4, 20, 21, 22 and 35 drawn to a method of enhancing pericyte cell proliferation comprising administering to a subject in need a BPI protein product, wherein the subject is suffering from disease associated with the presence of autoantibodies to pericytes, classified in Class 424, subclass 185.1.
  - III. Claims 1, 5, 20, 21, 22 and 35 drawn to a method of enhancing pericyte cell proliferation comprising administering to a subject in need a BPI protein product, wherein the subject is suffering from age-related macular degeneration, classified in Class 424, subclass 185.1.
  - IV. Claims 1, 6, 20, 21, 22 and 35 drawn to a method of enhancing pericyte cell proliferation comprising administering to a subject in need a BPI protein product, wherein the subject is suffering from ovarian failure, classified in Class 424, subclass 185.1.
  - V. Claims 1, 7, 20, 21, 22 and 35 drawn to a method of enhancing pericyte cell proliferation comprising administering to a subject in need a BPI protein product, wherein the subject is suffering from multiple sclerosis, classified in Class 424, subclass 185.1.

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- VI. Claims 1 ,8, 20, 21 , 22, and 35 drawn to a method of enhancing pericyte cell proliferation comprising administering to a subject in need a BPI protein product, wherein the subject is suffering from conditions involving perturbation of the blood-brain-barrier or partial seizures, classified in Class 424, subclass 185.1.
- VII. Claims 1 9 , 20, 21 22 and 35 drawn to a method of enhancing pericyte cell proliferation comprising administering to a subject in need a BPI protein product, wherein the subject is pregnant and placental development is enhanced, classified in Class 424, subclass 185.1.
- VIII. Claims 1 ,10 , 20, 21 ,22 and 36 drawn to a method of enhancing pericyte cell proliferation comprising administering to a subject in need a BPI protein product, wherein the subject is in need of wound healing, classified in Class 424, subclass 185.1.
- IX. Claims 1 ,11 , 20, 21 ,22 and 37 drawn to a method of enhancing pericyte cell proliferation comprising administering to a subject in need a BPI protein product, wherein the subject is suffering from a bone degenerative disorder, classified in Class 424, subclass 185.1.
- X. Claims 12 , 13 and 38 , drawn to a method of inhibiting pericyte cell proliferation comprising administering to a subject in need an agent that inhibits BPI protein product-induced proliferation of pericyte cells, wherein the subject is suffering from hypertension, classified in Class 424, subclasses 185.1 130.1 and 139.1.
- XI. Claims 12 , 14 and 38 , drawn to a method of inhibiting pericyte cell proliferation comprising administering to a subject in need an agent that inhibits BPI protein product-induced proliferation of pericyte cells, wherein the subject is suffering from vascular disease, classified in Class 424, subclasses 185.1 130.1 and 139.1.
- XII. Claims 12 , 15 and 38 , drawn to a method of inhibiting pericyte cell proliferation comprising administering to a subject in need an agent that inhibits BPI protein product-induced proliferation of pericyte cells, wherein the subject is suffering from acute respiratory distress syndrome, classified in Class 424, subclasses 185.1 130.1 and 139.1.
- XIII. Claims 12 , 16 and 38 , drawn to a method of inhibiting pericyte cell proliferation comprising administering to a subject in need an agent that inhibits BPI protein product-induced proliferation of pericyte cells, wherein the subject is suffering from endometriosis or adenomyosis, classified in Class 424, subclasses 185.1 130.1 and 139.1.
- XIV. Claims 17 , 18, 27, 28 and 39 drawn to a method of enhancing retinal epithelial cell proliferation comprising administering to a subject in need a BPI protein product, wherein the subject is suffering from retinitis pigmentosa, classified in Class 424, subclass 185.1.

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- XV. Claims 17 , 19, 27, 28 and 39 drawn to a method of enhancing retinal epithelial cell proliferation comprising administering to a subject in need a BPI protein product, wherein the subject is suffering from age-related macular degeneration, classified in Class 424, subclass 185.1.
- XVI. Claims 23 and 32 drawn to a method of screening for a candidate inhibitor of BPI-induced proliferation of pericytes, classified in Class 435, subclass 7.1, 41 and 375.
- XVII. Claims 24 and 32 drawn to a method of screening a BPI protein product for the ability to enhance proliferation of pericytes, classified in Class 435, subclass 7.1, 41 and 375.
- XVIII. Claim 25 ,26 and 32 drawn to a method of screening for a candidate enhancer of pericyte proliferation, classified in Class 435, subclass 7.1, 41 and 375.
- XIX. Claims 29 and 32 drawn to a method of screening for a candidate inhibitor of BPI-induced proliferation of epithelial cells, classified in Class 435, subclass 7.1, 41 and 375.
- XX. Claims 30 and 32 drawn to a method of screening for a BPI protein product for the ability to enhance proliferation of epithelial cells, classified in Class 435, subclass 7.1, 41 and 375.
- XXI. Claims 31 and 32 drawn to a method of screening for a candidate enhancer of epithelial cell proliferation, classified in Class 435, subclass 7.1, 41 and 375.

3. Groups I- XXI are different methods. These inventions are different with respect to the pathological conditions that are differ in etiologies and therapeutic endpoints, ingredients, and method steps, which require non-coextensive searches ; therefore, each method is patentably distinct.

4. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon various pathological conditions that are differ in etiologies and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

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### **Species Election**

5. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

6. If Group I is elected, applicant is required to elect a specific to a method of enhancing pericyte cell proliferation comprising administering to a subject in need a BPI protein product, wherein specific pathological condition, selected from the group recited in claims 3 and 35.

These species are distinct because the specific methods of enhancing pericyte cell proliferation comprising administering to a subject in need a BPI protein product, wherein specific pathological condition, selected from the group recited in claims 3 and 35 differ with respect to in etiologies and therapeutic endpoints of pathological conditions ; thus each condition represents patentably distinct subject matter.

7. If Group VI is elected, applicant is required to elect a specific to a method of enhancing pericyte cell proliferation comprising administering to a subject in need a BPI protein product, wherein specific pathological condition, selected from the group recited in claims 8 and 35.

These species are distinct because the specific methods of enhancing pericyte cell proliferation comprising administering to a subject in need a BPI protein product, wherein specific pathological condition, selected from the group recited in claims 8 and 35 differ with respect to in etiologies and therapeutic endpoints of pathological conditions ; thus each condition represents patentably distinct subject matter.

8. If Groups II, III, IV, V, or VII is elected, applicant is required to elect a specific method wherein specific pathological condition, selected from the group recited in claim 35.

These species are distinct because the specific methods wherein specific pathological condition, selected from the group recited in claim 35 differ with respect to in etiologies and therapeutic endpoints of pathological conditions ; thus each condition represents patentably distinct subject matter.

9. If Group XI is elected, applicant is required to elect a specific to a method of inhibiting pericyte cell proliferation comprising administering to a subject in need a BPI protein product, wherein specific pathological condition, selected from the group recited in claims 14 and 38.

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These species are distinct because the specific methods of inhibiting pericyte cell proliferation comprising administering to a subject in need a BPI protein product, wherein specific pathological condition, selected from the group recited in claims 14 and 38 differ with respect to in etiologies and therapeutic endpoints of pathological conditions ; thus each condition represents patentably distinct subject matter.

10. If Group X, XII, or XIII is elected, applicant is required to elect a specific to a method wherein specific pathological condition, selected from the group recited in claim 38.

These species are distinct because the specific methods, wherein specific pathological condition, selected from the group recited in claim 38 differ with respect to in etiologies and therapeutic endpoints of pathological conditions ; thus each condition represents patentably distinct subject matter.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).


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A telephone call was made to Jeffrey S. Sharp on 09/26/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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September 30, 2003

  
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